

Amendment and Response

Page 2 of 11

Serial No.: 09/453,726

Confirmation No.: Unknown

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

green, Spirit soluble HLK BASF, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD, Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Basic red 15, Mordant red 19, Bromopyrogallol red, and combinations thereof.

A' 2. **(AMENDED)** The hydrogen peroxide sterilization indicator of claim 1, wherein the colorant is selected from the group consisting of Malachite green oxalate, Methyl violet 2B, New fuchsin, Toluidine blue O, Luxol brilliant green BL, Quinea green B, Thionine, Meldolas blue, Lissamine green B, Alkali blue 6B, Brilliant green, Victoria green S extra, Eriochrome blue black B, Congo red, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Bromopyrogallol red, and combinations thereof.

3. **(AMENDED)** The hydrogen peroxide sterilization indicator of claim 2, wherein the colorant is selected from the group consisting of Malachite green oxalate, Methyl violet 2B, New fuchsin, Quinea green B, Thionine, Meldolas blue, Lissamine green B, Alkali blue 6B, Congo red, Eriochrome blue black B, Bismarck brown R, Methylene violet 3RAX, and combinations thereof.

4. **(AMENDED)** The hydrogen peroxide sterilization indicator of claim 2, wherein the colorant is selected from the group consisting of Toluidine blue O, Luxol brilliant green BL, Victoria green S extra, Methylene violet, Bromopyrogallol red, Brilliant green, and combinations thereof.

Amendment and Response

Page 3 of 11

Serial No.: 09/453,726

Confirmation No.: Unknown

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

5. **(AMENDED)** The hydrogen peroxide sterilization indicator of claim 1, wherein the colorant is selected from the group consisting of Ethyl violet, New fuchsin, Toluidine blue O, Luxol brilliant green BL, Disperse blue 1, Brilliant blue R, Quinea green B, Thionine, Meldolas blue, Methylene green, Lissamine green B, Alkali blue 6B, Brilliant green, Spirit soluble HLK BASF, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD, Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Mordant red 19, Bromopyrogallol red, and combinations thereof.

A¹
6. **(AMENDED)** The hydrogen peroxide sterilization indicator of claim 1, wherein the indicator composition further comprises at least one colorant that does not change color upon contact with hydrogen peroxide vapor.

7. **(AMENDED)** The hydrogen peroxide sterilization indicator of claim 6, wherein the colorant that does not change color upon contact with hydrogen peroxide vapor is selected from the group consisting Quinacridone red 19, Auramine O, Brilliant blue G, Acid black 24, Patent blue violet, Disperse red 13, Sudan black B, Janus green B, Acridine orange base, Fast green FCF, Patent blue VF, Acid red 97, Sulforhodamine B, Xylenol orange sodium salt, Azure B, Spirit soluble fast yellow G, Keystone soap fluoro green, Calco oil blue N, Oil blue A, Calco oil green, D & C red no. 33, D & C green no.5, Bordeaux R, Xylenol cyanole FF, Crystal scarlet, Basic blue 41, Evans blue, Chicago sky blue 6B, Acid blue 113, Acid blue 120, Acid red 88, Acid red 151, Acid violet 5, Disperse red 1, Direct red 81, Disperse red 19, Sudan red 7B, Basic red 73, Acid green AX986, and combinations thereof.

8. (AMENDED) The hydrogen peroxide sterilization indicator of claim 7, wherein the indicator composition comprises Alkali blue 6B and Quinacridone red 19.

9. (AMENDED) The hydrogen peroxide sterilization indicator of claim 1, wherein the substrate is a polyester film.

Sub c2
A1
10. (AMENDED) A hydrogen peroxide sterilization indicator comprising a substrate and an indicator composition disposed thereon, wherein the indicator composition comprises a binder, at least one colorant selected from the group consisting of Malachite green oxalate, Crystal violet, Methyl violet 2B, Ethyl violet, New fuchsin, Victoria blue B, Victoria pure blue BO, Toluidine blue O, Luxol brilliant green BL, Disperse blue 1, Brilliant blue R, Victoria blue R, Quinea green B, Thionine, Meldolas blue, Methylene green, Lissamine green B, Alkali blue 6B, Brilliant green, Spirit soluble HLK BASE, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD, Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Basic red 15, Mordant red 19, Bromopyrogallol red, and combinations thereof, and at least one colorant that does not change color upon contact with hydrogen peroxide vapor.

11. (AMENDED) A method of monitoring a hydrogen peroxide sterilization process, the method comprising exposing an article to be sterilized and the hydrogen peroxide sterilization indicator of claim 1 to hydrogen peroxide vapor.

Amendment and Response

Page 5 of 11

Serial No.: 09/453,726

Confirmation No.: Unknown

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

20. 21. (NEW) The hydrogen peroxide sterilization indicator of claim 1, wherein the colorant is selected from the group consisting of of Malachite green oxalate, Methyl violet 2B, Ethyl violet, New fuchsin, Victoria blue B, Victoria pure blue BO, Toluidine blue O, Luxol brilliant green BL, Disperse blue 1, Brilliant blue R, Victoria blue R, Quinea green B, Thionine, Meldolas blue, Methylene green, Lissamine green B, Alkali blue 6B, Spirit soluble HLK BASF, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD, Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Basic red 15, Mordant red 19, Bromopyrogallol red, and combinations thereof.

22. (NEW) The method of claim 11, wherein the article to be sterilized and the hydrogen peroxide sterilization indicator are exposed to hydrogen peroxide vapor at a temperature of about 45°C to about 50°C and a pressure of about 8×10^2 Pascals to about 13.3×10^2 Pascals.